

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 1:23-cv-1088

COMPLAINT

COMES NOW, the Plaintiff, Informed Consent Action Network, (“**ICAN**” or “**Plaintiff**”), and brings this action against Defendant, Food and Drug Administration (“**FDA**” or “**Defendant**”), to compel compliance with the Freedom of Information Act, 5 U.S.C. § 522 (“**FOIA**”). As grounds for its Complaint, Plaintiff would respectfully state and show unto this Honorable Court the following, to wit:

JURISDICTION AND VENUE

1. This Court has jurisdiction over the parties and subject matter pursuant to 5 U.S.C. § 522(a)(4)(B) and 28 U.S.C. § 1331.
2. Venue is proper with this Court pursuant to 5 U.S.C. § 522(a)(4)(B) and 28 U.S.C. § 1391.

PARTIES

3. Plaintiff is a not-for-profit organization formed and existing under the laws of the state of Texas with its principal place of business being located at 2025 Guadalupe Street, Suite 260, Austin, Texas 78705. Plaintiff is in good standing with the Texas Secretary of State.

4. Defendant, FDA, is an agency within the Executive Branch of the United States Government within the meaning of 5 U.S.C. § 522(f). FDA has possession, custody, and control of records to which Plaintiff seeks access.

STATEMENT OF FACTS

5. On November 4, 2021, Plaintiff submitted its expedited request for records pursuant to the Freedom of Information Act upon Defendant as well as a waiver of fees. 5 U.S.C. § 522 (a)(6)(E) and (a)(4)(A)(iii). *See Exhibit A*. Plaintiff's request for expedited processing certified it to be true and correct to the best of its knowledge and belief. *Id.*; 5 U.S.C. § 522 (a)(6)(E)(vi).

6. Plaintiff's request for records ("**FOIA Request**") sought:

All documents sufficient to identify each and every complaint, concern, violation, grievance, criticism, or problem brought to the attention of the Food and Drug Administration regarding any Phase I, Phase II, and/or Phase III clinical trial for any COVID-19 vaccine.
(**Exhibit A**)

7. On November 12, 2021, Defendant acknowledged Plaintiff's FOIA Request, assigning FOIA Control #2021-7648. *See Exhibit B*. In its responsive correspondence, Defendant denied Plaintiff's request for expedited processing stating the FOIA Request did not meet the standard of compelling need. *Id.* Specifically, Defendant stated:

I have determined that your request for expedited processing does not meet the criteria under FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received. *Id.*

8. Defendant's response to Plaintiff's FOIA Request failed to evidence any reasonable effort made by Defendant to estimate the volume of the requested matter or provide any such estimate to Plaintiff as required by 5 U.S.C. § 522 (a)(6)(F).

9. Because Defendant denied Plaintiff's request for expedited processing and otherwise failed to respond in a timely manner to such request, its actions are subject to immediate judicial review based upon the record before the agency. 5 U.S.C. § 522 (a)(6)(C)(i) and (a)(6)(E)(iii).

10. Plaintiff is not required to pursue an administrative appeal before seeking judicial review of its request for expedited processing of a FOIA request.

11. The Freedom of Information Act provides for "expedited processing of requests for records in cases in which the person requesting the records demonstrates a compelling need" 5 U.S.C. § 522 (a)(6)(E)(i)(I). "[W]ith respect to a request made by a person primarily engaged in disseminating information," the term "compelling need" means "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 522 (a)(6)(E)(v)(II).

12. Plaintiff requested expedited processing on the basis that it is "primarily engaged in disseminating information to the general public" and that there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 522 (a)(6)(E)(v)(II).

13. Defendant does not and cannot challenge that Plaintiff is "primarily engaged in disseminating information." Specifically, Plaintiff's mission is to raise public awareness about public health and safety and to provide the public with information to give informed consent regarding related health interventions and precautions. *See Exhibit A*. Plaintiff will disseminate any information it obtains in response to the FOIA Request. Plaintiff has a recognized interest in timely contributing to the ongoing public debate about the actions of federal health agencies related to SARS-CoV-2 and Covid-19. Therefore, Plaintiff is "primarily engaged in disseminating information to the general public," and as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity."

14. Defendant “is responsible for protecting public health by ensuring the safety[] [and] efficacy . . . of . . . biological products[.]”¹ As part of that responsibility, the FDA approves drugs and biologics, typically, before they become available to the public.² Congress mandated that the FDA only approve a product if its sponsor has proven it to be “safe and effective.” *See, e.g.*, 21 U.S.C. § 393.

15. Here, by way of example, on August 23, 2021, the FDA approved the Pfizer-BioNTech vaccine, marketed as Comirnaty (the “**Pfizer Vaccine**”), for individuals 16 years of age and older. It subsequently licensed the Pfizer Vaccine for use in children 12-15-years old. Pfizer’s vaccine is also authorized for emergency use in children ages 6 months old through 11 years old.³

16. The FDA claims that it is committed to “open[ing] the doors of the agency.” In that regard, it maintains an entire section on its website dedicated to transparency.⁴ However, reports claim that Ventavia Research Group “falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer’s pivotal phase II trial” and that the FDA was aware of these claims.⁵ In its FOIA Request, Plaintiff seeks information regarding these claims, *inter alia*.

17. In determining whether there is “urgency to inform the public,” courts consider: “(1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and

¹ <https://www.fda.gov/about-fda/what-we-do>.

² <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved>.

³ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use>; <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>.

⁴ <https://www.fda.gov/about-fda/transparency>.

⁵ <https://www.bmj.com/content/375/bmj.n2635>.

(3) whether the request concerns federal government activity.” *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.D.C. 2001). All three factors are present in the case *sub judice*.

18. **A matter of current exigency to the American public.** The urgency to inform the public concerning the data and information underlying a licensed vaccine is reflected in the Code of Federal Regulations which expressly provides that “[a]fter a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information” 21 C.F.R. § 601.51(e). Thus, Defendant’s own regulations expressly recognize the importance of having data and information relied upon to license a vaccine “immediately available for public disclosure.” *Id.*

19. Moreover, there is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Covid-19 vaccines. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms who have declared that the data and information underlying the licensure of the Covid-19 vaccines is more than sufficient for licensure.

20. For instance, in a press release issued on August 23, 2021, acting FDA Commissioner Janet Woodcock stated that “the public can be very confident that [the Pfizer Vaccine] meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product.”⁶ Peter Marks, the director of FDA’s Center for Biologics Evaluation and Research, made similar remarks, stating that:

⁶ <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>.

[The FDA’s] scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of [the Pfizer Vaccine]. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of [the Pfizer Vaccine’s] safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities[.]⁷

Peter Marks further stated that “although [the FDA] approved [the Pfizer Vaccine] expeditiously, it was fully in keeping with [the FDA’s] existing high standards for vaccines in the U.S.”⁸ President Biden also stated that the FDA’s approval meets the “gold standard.”⁹ Even prior to FDA approval of the Pfizer Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines are “safe and effective.”¹⁰

21. On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, adequacy of the review, and appropriateness of the analyses relied upon to license, as an example, the Pfizer Vaccine. For example, on June 1, 2021, a group of 27 clinicians and scientists filed a Citizen Petition¹¹ with the FDA, claiming that the available evidence for licensure of the Pfizer Vaccine “is simply not mature

⁷ *Id.*

⁸ *Id.*

⁹ <https://www.cbsnews.com/news/biden-address-covid-19-vaccine-pfizer-fda-approval-watch-live-stream-today-2021-08-23/>.

¹⁰ See, e.g., <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible>. See also <https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection> (“COVID-19 vaccines have proven to be safe, effective and life-saving.”); <https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness> (“COVID-19 vaccines are safe”); <https://www.wlns.com/news/gov-whitmer-and-dr-khaldun-respond-to-the-fda-approval-of-pfizers-covid-19-vaccine/> (quoting Governor Whitmer referring to the Pfizer Vaccine as a “safe, effective COVID-19 vaccine”).

¹¹ <https://www.regulations.gov/document/FDA-2021-P-0521-0001>.

enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations.”¹²

22. Peter Doshi, PhD at University of Maryland, has publicly questioned the lack of transparency regarding the vaccine approval process,¹³ which Peter Marks publicly disputed.¹⁴ During the clinical trials, Peter Doshi questioned the adequacy of the data on the basis that the Pfizer Vaccine is only “13 months into the still ongoing, two year pivotal trial, with no reported data past 13 March 2020, unclear efficacy after six months due to unblinding, evidence of waning protection irrespective of the Delta variant, and limited reporting of safety data.”¹⁵

23. Andrew Kheriaty, professor of psychiatry at UCI School of Medicine, Director of the Medical Ethics Program at UCI Health,¹⁶ has also questioned the FDA’s approval process. For example, in an article published in *The Wall Street Journal*, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review¹⁷ by the FDA’s Vaccines and Related Biological Products Advisory Committee (“VRBPAC”) that indicates a risk of heart inflammation after vaccination.¹⁸

¹² See <https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/>.

¹³ See <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/>; <https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/>; <https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/>.

¹⁴ <https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/>.

¹⁵ <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/>.

¹⁶ <https://www.aaronkheriaty.com/bio>.

¹⁷ <https://www.fda.gov/media/150054/download>.

¹⁸ <https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220>.

24. Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is “essential” for the FDA to, among other things, “make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public[.]”¹⁹

25. Despite all eyes on the Covid-19 vaccines and calls for transparency regarding the FDA’s actions, the FDA did not convene its advisory group, VRBPAC, to have a public meeting prior to issuing a license for each Covid-19 vaccine. Those interested were denied the opportunity to both hear discussion about the data and to offer public comment about same.

26. The public debate regarding the adequacy of the FDA’s review process for the Covid-19 vaccines and the answer to “what issues were brought to the FDA’s attention during these critical trials and when?” is unlikely to be settled without full disclosure of the information sought in this FOIA Request.

27. **The consequences of delaying a response compromise significant recognized interests.** Delaying public access to the requested information would compromise a number of significant recognized interests, including ICAN’s right, as a media outlet, to timely contribute to the public’s understanding of the Pfizer Vaccine and the public’s right to have a full understanding of a product being mandated in numerous settings by both governments and private businesses. Moreover, the American public has a significant recognized interest in obtaining complete and accurate information to meaningfully engage in the democratic process. Several investigations are ongoing about the origin of, and governmental response to Covid-19. Because the findings of these investigations will evaluate the responses of both the Trump and Biden Administrations, as well

¹⁹https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf. See also <https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/>.

as top agency personnel, these investigations could have major political ramifications on future elections. As Americans prepare for the 2024 Presidential elections, voters have a significant recognized interest in obtaining the information necessary to guide their decisions. Therefore, it is essential that the public and investigators have access to all the relevant materials regarding the origins of, and governmental response to Covid-19. For this reason, ICAN has demonstrated that delaying a response to its request would compromise significant recognized interests.

28. **The request concerns government activity.** Plaintiff's FOIA Request is related to government activity. The records sought are directly linked to information held by and actions taken by a federal health agency.

29. Defendant violated FOIA when it inappropriately denied Plaintiff's request for expedited processing of its FOIA Request.

30. Defendant violated FOIA when it did not otherwise provide a final response within the time limits prescribed by FOIA.

31. Defendant continues to violate FOIA by not providing any responsive records or final response to Plaintiff's FOIA Request.

COUNT I
IMPROPER DENIAL OF EXPEDITED PROCESSING
(VIOLATION OF FOIA, 5 U.S.C. § 552)

32. Plaintiff realleges the paragraphs above as if fully stated herein.

33. Defendant FDA improperly denied expedited processing for Plaintiff's FOIA Request.

34. Plaintiff demonstrated that it is a person primarily engaged in disseminating information.

35. Plaintiff demonstrated a compelling need for the responsive documents.

36. Therefore, Plaintiff is entitled to expedited processing.

37. Defendant is in violation of FOIA.

38. Plaintiff is being irreparably harmed by reason of Defendant's violation of FOIA and Plaintiff will continue to be irreparably harmed unless Defendant is compelled to comply with the law.

39. Plaintiff has no adequate remedy at law.

COUNT II
FAILURE TO MAKE DETERMINATION BY REQUIRED DEADLINE
(VIOLATION OF FOIA, 5 U.S.C. § 552)

40. Plaintiff realleges the paragraphs above as if fully stated herein.

41. Defendant was required to make a determination on Plaintiff's FOIA Request by December 7, 2021.

42. Defendant failed to make this determination on Plaintiff's FOIA Request within the time limits set forth by FOIA.

43. Therefore, Plaintiff is deemed to have exhausted its administrative remedies. *See* 5 U.S.C. § 552(a)(6)(C)(i).

44. Defendant is in violation of FOIA.

45. Plaintiff is being irreparably harmed by reason of Defendant's violation of FOIA and Plaintiff will continue to be irreparably harmed unless Defendant is compelled to comply with the law.

46. Defendant made no good faith attempts to discuss with Plaintiff how it could effectively limit the scope of the request.

47. Plaintiff has no adequate remedy at law.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for the following relief:

- a. Declare that Defendant's denial of expedited processing of Plaintiff's FOIA Request is unlawful under FOIA;
- b. Declare that Defendant's existing and continued delay in processing Plaintiff's FOIA Request is unlawful under FOIA;
- c. Order Defendant to conduct searches for all records responsive to Plaintiff's FOIA request on an expedited basis and in no event later than 10 days from the date of the order;
- d. Order Defendant to produce, by a date certain, all non-exempt records responsive to Plaintiff's FOIA request and a Vaughn index of any responsive records withheld under any claimed exemption;
- e. Order Defendant to waive any fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii);
- f. Provide for expeditious proceedings in this action;
- g. Maintain jurisdiction over this action until Defendant complies with FOIA and all orders of this Court;
- h. Grant Plaintiff an award of attorneys' fees and other litigation costs reasonably incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and
- i. Grant Plaintiff such other relief as the Court may deem just and proper.

Dated: September 11, 2023

SIRI & GLIMSTAD LLP

/s/ Aaron Siri
Aaron Siri, Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
(*pro hac vice* to be filed)
R. Scott Pietrowski, MS Bar No. 99387

(pro hac vice to be filed)
Siri & Glimstad LLP
745 Fifth Avenue, Suite 500
New York, New York 10151
Tel: (212) 532-1091
aaron@sirillp.com
ebrehm@sirillp.com
spietrowski@sirillp.com

Attorneys for Plaintiff